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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,145	08/22/2003	Bong Cheol Kim	2298.0140001/TJS/M-N	8727

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EXAMINER	
SOROUSH, LAYLA	

ART UNIT	PAPER NUMBER
1627	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,145	KIM ET AL.	
	Examiner	Art Unit	
	LAYLA SOROUSH	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *146-148,150-174,176,177,180-203,233 and 237-244* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *146-148,150-174,176,177,180-203,233 and 237-244* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/23/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 23, 2010 has been entered.

See rejections below:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 146, 150, 168-169, 233, 237, 241, and 242 and are rejected under 35 U.S.C. 102(b) as being anticipated by Motohashi ("Medicinal Uses of the Kiwifruit Family (Actinidia)," West Australian Nut and Tree Crops Association 16:48-59, West Australian Nut and Tree Crops Association, Australia (1991) – IDS) in view of Hunder et al. (Immunoglobulin E (IgE) levels in serum and synovial fluid in rheumatoid arthritis Arthritis & Rheumatism Volume 17, Issue 6, pages 955–963, November/December 1974).

Motohashi teaches the use of *Actinidia arguta* in treatment of stomach disorders, reducing fevers, increase urination, treat indigestion, stop nausea, and treat jaundice and rheumatoid arthritis. It is taken orally (see pages 48-49). The teaching of boiling the roots or leaves in a concentrate or extracts for oral administration inherently reads on a conventional carrier.

Hunder et al. is solely used to show that there is an increase of IgE in patients with rheumatoid arthritis. Hence, treatment of rheumatoid arthritis would result in the decrease of IgE in patients with rheumatoid arthritis.

Claims 147, 150, 168-169, 233, 237, 241, and 242 are rejected under 35 U.S.C. 102(b) as being anticipated by Motohashi ("Medicinal Uses of the Kiwifruit Family (Actinidia)," West Australian Nut and Tree Crops Association 16:48-59, West Australian Nut and Tree Crops Association, Australia (1991) – IDS) in view of Myers et al. (The genetic ablation of cyclooxygenase 2 prevents the development of autoimmune arthritis. Arthritis & Rheumatism Volume 43, Issue 12, pages 2687–2693, December 2000).

Motohashi teaches the use of *Actinidia arguta* in treatment of stomach disorders, reducing fevers, increase urination, treat indigestion, stop nausea, and treat jaundice and rheumatoid arthritis. It is taken orally (see pages 48-49). The teaching of boiling the roots or leaves in a concentrate or extracts for oral administration inherently reads on a conventional carrier.

Myers et al. teaches the immune response was assessed by measuring total CII IgG, IgG1, and IgG2 antibody production in sera from immunized mice. The passive transfer of arthritis, accomplished using anti-CII monoclonal

antibodies, was tested in wild-type and COXdeficient (-/-) mice. Since IL-4 is important in up-regulating IgG1 production while IgG2 is up-regulated by the inflammatory cytokine interferon-g (IFNg), we evaluated the anti-CII antibodies for the presence of the 2 IgG subtypes. Compared with wild-type controls, COX-1-/- mice exhibited a slight increase in IgG2a antibody production and a slight decrease in IgG1 antibodies (Table 1). Conversely, COX-2-/- mice exhibited significantly depressed levels of both IgG1 and IgG2 antibodies (Table 1). The isotypes expressed in COX-1-/- mice are consistent with the finding that a lack of PGE2 causes depressed levels of IgG1 (15). However, the COX-2-/- mice exhibited a more severe depression of the anti-CII IgG response. Therefore, a major factor in the inhibition of CIA in COX-2-/- mice is the inability of these mice to produce antibodies to CII. Hence, Myers et al. is solely used to show treatment of arthritis would result in the decrease of IgG1 and increase of IgG2a in patients with arthritis.

Claims 148, 150, 158, 168-169, 233, 237, 241, and 242 are rejected under 35 U.S.C. 102(b) as being anticipated by Motohashi ("Medicinal Uses of the Kiwifruit Family (Actinidia)," West Australian Nut and Tree Crops Association 16:48-59, West Australian Nut and Tree Crops Association, Australia (1991) – IDS) in view of Yudoh et al. (Reduced expression of the regulatory CD4+ T cell subset is related to Th1/Th2 balance and disease severity in rheumatoid arthritis. Arthritis & Rheumatism Volume 43, Issue 3, pages 617–627, March 2000)

Motohashi teaches the use of *Actinidia arguta* in treatment of stomach disorders, reducing fevers, increase urination, treat indigestion, stop nausea, and

treat jaundice and rheumatoid arthritis. It is taken orally (see pages 48-49). The teaching of boiling the roots or leaves in a concentrate or extracts for oral administration inherently reads on a conventional carrier.

Yudoh et al. teaches in rheumatoid arthritis, reduced expression of the CD41 T cell subset producing IL-10 but not IL-2 and IL-4 may be responsible for the dominance of Th1 over Th2 cells at sites of inflamed synovium and in the peripheral blood. Decreases in this type of CD41 T cell subset may induce the down-regulation of T cell tolerance and exacerbate the inflammatory process in rheumatoid arthritis. Hence, Yudoh et al. is solely used to show treatment of arthritis would result in the decrease of TH2 and increase of TH1 in patients with rheumatoid arthritis.

Claims 176, 180, 197-198, 233, 237, 241, and 242 are rejected under 35 U.S.C. 102(b) as being anticipated by Motohashi ("Medicinal Uses of the Kiwifruit Family (Actinidia)," West Australian Nut and Tree Crops Association 16:48-59, West Australian Nut and Tree Crops Association, Australia (1991) – IDS) in view of Permin et al. (Possible Role of Histamine in Rheumatoid Arthritis. Allergy Volume 36, Issue 6, pages 435–436, August 1981).

Motohashi teaches the use of *Actinidia arguta* in treatment of stomach disorders, reducing fevers, increase urination, treat indigestion, stop nausea, and treat jaundice and rheumatoid arthritis. It is taken orally (see pages 48-49). The teaching of boiling the roots or leaves in a concentrate or extracts for oral administration inherently reads on a conventional carrier.

Permin et al. is solely used to show a role of histamine in rheumatoid arthritis is also supported by the findings of clinical improvement during treatment with H_1 and H_2 antihistamines in six of 12 patients with rheumatoid arthritis in active phase, whereas four showed definite deterioration. Hence, treatment of rheumatoid arthritis would result in the decrease of histamine in patients with rheumatoid arthritis.

Claims 177, 197-198, 233, 237, 241, and 242 are rejected under 35 U.S.C. 102(b) as being anticipated by Motohashi ("Medicinal Uses of the Kiwifruit Family (Actinidia)," West Australian Nut and Tree Crops Association 16:48-59, West Australian Nut and Tree Crops Association, Australia (1991) – IDS) in view of McGonagle et al. (The relationship between synovitis and bone changes in early untreated rheumatoid arthritis: A controlled magnetic resonance imaging study. Arthritis & Rheumatism Volume 42, Issue 8, pages 1706–1711, August 1999).

Motohashi teaches the use of *Actinidia arguta* in treatment of stomach disorders, reducing fevers, increase urination, treat indigestion, stop nausea, and treat jaundice and rheumatoid arthritis. It is taken orally (see pages 48-49). The teaching of boiling the roots or leaves in a concentrate or extracts for oral administration inherently reads on a conventional carrier.

McGonagle et al. is solely used to show metacarpophalangeal joint bone edema is present in the majority of patients with RA at presentation, but is seen only occasionally in normal control subjects. The fact that bone edema occurred

rarely in the absence of synovitis in patients with RA suggests that bony changes in RA are secondary to synovitis. Hence, treatment of rheumatoid arthritis would result in the decrease of edema in patients with rheumatoid arthritis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 155-157, 170-171, 173, 185-187, 199-200, 202, 239, and 243-244 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Motohashi ("Medicinal Uses of the Kiwifruit Family (Actinidia)," West Australian Nut and Tree Crops Association 16:48-59, West Australian Nut and Tree Crops Association, Australia (1991) – IDS), as applied to claims 146-148, 150, 158, 168-169, 176-177, 180, 197-198, 233, 237, 241, and 242.

Motohashi is as discussed above.

Although, Motohashi teaches that Actinidia is easy to grow, process the fruit into products, or to cook with the fruit, Motohashi fails to specify the amount of the extract, the extract in a health food, in a food additive as claimed.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the specific Actindia in a health food or as a food additive. The motivation comes from the teaching of Motohashi that processing the fruit into products, or to cook with the fruit is known in the art.

Hence, a skilled artisan would have reasonable expectation of successfully producing a health food or food additive as claimed. Additionally, to the skilled artisan, the claimed subject matter would have been obvious because the skilled artisan would have appreciated that certain factors would influence the dosage required to effectively treat the subject for the purpose taught by the references, including, but not limited to the severity of the disease or disorder, previous treatments, the weight, general health and/or age of the subject and the presence of other diseases. The dosage would thus have been expected to be variable and, in the absence of evidence to the contrary, the determination of the optimum dosage to employ would have been a matter well within the purview of the skilled artisan.

Claims 172, 174, 201, and 203 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motohashi ("Medicinal Uses of the Kiwifruit Family (Actinidia)," West Australian Nut and Tree Crops Association 16:48-59, West Australian Nut and Tree Crops Association, Australia (1991) – IDS), as applied to claims 146-148, 150, 155-158, 168-171, 173, 176-177, 180, 185-187, and 197-200, 202, 233, 237, 239, and 241-244 in view of Murad (US 6,630,163-IDS).

Motohashi is as discussed above.

Motohashi fails to teach the specific food additive of the instant claims.

Murad teaches fruit extracts, including kiwi fruit extract and a pharmaceutically acceptable carrier. See col. 8, lines 10-29. The fruit extract is present in an amount of 0.01-80 wt. %. See col. 8, lines 13-16. Murad teaches the same amounts of the extract. The reference teaches oral administration of

such extracts with carriers such as glucose. Oral solid preparations include powders, capsules, and tablets. It is readily envisaged that such formulation must be taken with a liquid medium (i.e. a glass of water) for oral administration. Hence, reading on the limitation of addition to a drink.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the specific Actindia with glucose or a food additive. The motivation comes from the teaching of Motohashi that processing the fruit into products, or to cook with the fruit is known in the art. Hence, a skilled artisan would have reasonable expectation of successfully producing a food additive as claimed.

Claims 151-153, 159-167, 181-183, 188-196, 238 and 240 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motohashi ("Medicinal Uses of the Kiwifruit Family (Actinidia)," West Australian Nut and Tree Crops Association 16:48-59, West Australian Nut and Tree Crops Association, Australia (1991) – IDS), as applied to claims 146-148, 150, 155-158, 168-171, 173, 176-177, 180, 185-187, and 197-200, 202, 233, 237, 239, and 241-244 in view Tsuboi et al. (JP 02202808 A).

Motohashi is as discussed above.

Motohashi fails to teach the extraction process.

Tsuboi et al. teaches an oral or topical composition of kiwi extract comprising administering two times amount of water is added to kiwi fruit after heat treatment. The fruit is crushed, filtered, and then ethanol is added to same amount of resultant crude solution. The solution is stirred, then aged by leaving

at rest in cooling place for a whole day and night, preferably 2-3 days, and filtered by filter paper, with concentrating as necessary (abstract). The amount ethanol used ranges from 0-80%. Tsuboi et al. teaches the kiwi extract has excellent solubility in water system.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use *Actinidia* and the extraction method of Tsuboi et al. The motivation to use the extraction method of Tsuboi et al. for compositions of Motohashi is because Tsuboi et al. teaches the kiwi extract has excellent solubility in water system. Therefore, the skilled artisan would have reasonable expectation of achieving the desired therapeutic results. Selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection. See e.g., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claims 154 and 184 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motohashi ("Medicinal Uses of the Kiwifruit Family (Actinidia)," West Australian Nut and Tree Crops Association 16:48-59, West Australian Nut and Tree Crops Association, Australia (1991) – IDS) and Tsuboi et al. (JP 02202808 A), as applied to claims 146-148, 150-153, 155-171, 173, 176-177, 180-183, 185-200, 202, 233, and 237-244, and in view Suzuki et al. (US 20020054923 A1).

Motohashi is as discussed above.

Motohashi fails to teach the non-polar solvent ethyl acetate.

Suzuki et al. teaches kiwi fruit can be extracted with water, ethanol, methanol, acetic acid, chloroform, dichloromethane, ethyl acetate, n-hexane, acetone, benzene, petroleum ether, ether or the like.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use the non-polar solvent ethyl acetate. The motivation to use the solvent ethyl acetate of Suzuki et al. for compositions of Motohashi is because Suzuki et al. teaches kiwi fruit can be extracted with water, ethanol, methanol, acetic acid, chloroform, dichloromethane, ethyl acetate, n-hexane, acetone, benzene, petroleum ether, ether or the like. Therefore, the skilled artisan would reasonable expectation of achieving the desired therapeutic results.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 146-148,150-174,176,177,180-203,233 and 237-244 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 130-132,134-142,145,146 and 149-157 of U.S. Patent Application No. 11522511.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a method for reducing IgE production in a mammal in need thereof, said method comprising orally administering an extract of kiwifruit of the genus Actinidia to said mammal, wherein said extract is provided in an amount sufficient to inhibit or reduce IgE production in said mammal.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 146-148,150-174,176,177,180-203,233 and 237-244 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30, 34-37, 42-44, 55, 58, 60,63,65 and 67 of U.S. Patent Application No. 12/180723.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a method to regulate an immune response in a mammal, comprising administering a hardy kiwifruit extract preparation to the mammal in an amount sufficient to regulate an immune response in the mammal.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed August 23, 2010 have been fully considered. The response to the arguments is as discussed below:

Applicant's arguments with respect to Murad, Endres et al. (DE 19758090 A1), Udagawa (JP 61140510 A) Luo et al. (CN1107308A), Wuthrich, Lukacs and Capetola are moot in view of new rejections made above.

Applicant argues the Declaration filed August 31, 2010 shows a side by side comparison of the unexpectedly higher potency effects of extracts of *Actinidia arguta* over *Actidia deliciousa*. The Examiner points to the new 102(b) anticipatory rejection over Motohashi ("Medicinal Uses of the Kiwifruit Family (Actinidia)," West Australian Nut and Tree Crops Association 16:48-59, West

Australian Nut and Tree Crops Association, Australia (1991) – IDS) wherein the use of *Actinidia arguta* in treatment of stomach disorders, reducing fevers, increase urination, treat indigestion, stop nausea, and treat jaundice and rheumatoid arthritis is taught. The mere administration of *Actinidia arguta* would result in reducing serum IgE production, decreasing the serum level of IgG1 and increasing the serum level of IgG2a, decreasing Th2 serum cytokines and increasing Th1 serum cytokines. Additionally, the reference teaches the methods for treating, alleviating, or reducing one or more symptoms of allergic disease.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627